UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,223	09/12/2003	Stephen D. Pacetti	50623.330	9127

7590 04/29/2005

Paul J. Meyer, Jr.
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
EDWARDS, LAURA ESTELLE	
ART UNIT	**PAPER NUMBER**
1734	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,223	PACETTI ET AL.	
	Examiner	Art Unit	
	Laura Edwards	1734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7 and 25-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-7, and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-7, and 25-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,673,154 for reasons set forth in the previous office action.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-6, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch US 4,906,423).

Frisch teaches a support mandrel for manufacturing a prosthetic device or stent comprising a member configured to support a stent, the member having a plurality of pores disposed on a surface thereof wherein the pores are capable of receiving a coating substance

during a coating process wherein the pores can include open to closed cells (see col. 3, lines 60-62). Even though Frisch recognizes that at least some of the cells should be open (col. 3, lines 60-65, Frisch remains to include in the range of cell construction, closed cells as would be determined via routine experimentation in accordance with the foam material employed such that the claimed invention would be merely an obvious modification of the teachings of Frisch and patentability would not result. Furthermore, Applicants' use of the term "comprising" is deemed open ended language which would not exclude the teachings of Frisch to the use of a few open cells in combination with a closed pore system.

With respect to claim 2, even though Frisch teaches that the pore size and density of the porous surface is controlled by cell size and density of foam material employed (see col. 3, lines 67+ to col. 4, lines 1-22), Frisch is silent concerning the pore diameter of .2 to 50 microns. However, one of ordinary skill in the at would determine via routine experimentation the appropriate foam material to use having a desired pore diameter in accordance with the medical device being produced and the amount of coating material sought to be absorbed on the supported mandrel.

With respect to claims 4-6, 25, and 26, see col. 3, lines 60 to col. 4, lines 1-30.

Claims 1, 4-7, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al (US 6,521,284).

Parsons et al teach a support mandrel for manufacturing a prosthetic device or stent comprising a member configured to support a stent, the member having a plurality of pores disposed on a surface thereof wherein the pores are capable of receiving a coating substance

during a coating process wherein the pores can include open or closed cells of an desired size (see col. 5, lines 10-20) so as to enable the passing of fluids or liquids or not to enable the passing of fluids or liquids. In the above citation, Parsons et al recognize that the mandrel can be made of sintered metal, ceramic, polymeric materials, or glass having pores of a desired size. Even though Parsons et al do not explicitly teach that the cells should be of a closed cell construction, one of ordinary skill in the art would expect that the Parsons et al mandrel would be of a closed pore construction in the instance when it does not permit the passage of the liquid but enables the passage of the gas. In light of the teachings of Parsons et al, it would have been obvious to one of ordinary skill to form a stent using a mandrel of a closed cell construction so as to enable the passage of a desired fluid or liquid to form a final stent product.

Even though Parsons et al teach that the mandrel may have pores of any size, Parsons et al fail to teach or suggest the mandrel having a pores of a diameter of 0 .2 to 50 microns. However, one of ordinary skill in the at would determine via routine experimentation the appropriate pore size including diameter in accordance with the medical device being produced and the amount of material sought to be retained on the support mandrel.

With respect to the types of materials (i.e., polymer, metal or ceramic) used to make the mandrel, it is within the purview of one of ordinary skill in the art to utilize any known polymer, metal, and/or ceramic material from which to make the mandrel in so long as such materials do not destroy, degrade, or interact in any negative manner with the stent and the materials used to coat the stent.

Response to Arguments

Applicants' arguments filed 1/5/05 have been fully considered but they are not persuasive.

Applicants contend that Frisch fails to teach a closed pore system because Frisch teaches that some open cells are required in order for the polymeric composition to penetrate into the foam to form a porous surfaced body.

The first argument is not deemed persuasive because Frisch explicitly teaches that the foam mandrel can be of a closed cell construction in col. 3, lines 60-61. The pore size and density are controlled based on the foam material utilized as evidenced by col. 3, lines 67 to col. 4, lines 1-2. Furthermore, Applicants' open claim language, via the use of the term "comprising", does not exclude the inclusion of some open cells on the surface of the foam member. Therefore, Applicant's claimed invention to having a mandrel member of a closed cell construction capable of supporting a stent during processing is deemed obvious in light of the teachings of Frisch.

Applicants contend that Frisch fails to teach a mandrel having a closed pore system which would work as intended in that upon disintegration of the mandrel to remove the final product or polymeric body therefrom, the polymeric body or stent body would be disintegrated and only bits of polymer the size of individual pores would result. This argument is not deemed persuasive because the routineer in the art would recognize using suitable foam materials of closed celled construction to manufacture the stent such that upon removal of the foam mandrel with an appropriate solvent system, destruction or degradation of the final stent product would not result.

Applicants contend that Parsons et al do not teach a closed cell or closed pore system because the liquid composition is allowed to pass through the pores of the mandrel. This argument is not deemed persuasive because Parsons et al teach another embodiment wherein the mandrel is designed such that the liquid cross-linkable composition is not allowed to pass through the mandrel as evidenced by col. 5, lines 14-18 and therefore Parsons et al provide for a closed pore mandrel.

Conclusion

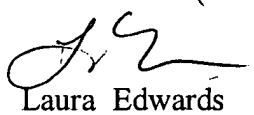
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Laura Edwards
Primary Examiner
Art Unit 1734

Le
April 25, 2005